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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,369	02/23/2004	Min Wan	D 2003.784 US	8537

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,369	WAN ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/23/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-9,11-12* is/are rejected.

7)☒ Claim(s) *2,3, and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

T.D

DETAILED ACTION

Claim Objections

Claim 10, line 2 is objected to because of the following informalities: it is not clear whether Applicant meant to spell "proline" (rather than "praline") or if Glyclglycine is an art recognized alternative name for Gly-Gly/Glycine-Glycine. Appropriate correction or comment is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (Exp. Eye Res. Vol. 50 (1990), pgs. 157-164).

Roberts et al. teach the use of ibuprofen to inhibit or delay carbamylation of proteins in cyanate solutions (entire document).

Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. (Exp. Eye Res. Vol. 43 (1986) , pgs. 973-979).

Lewis et al. teach the use of bendazac to inhibit or delay carbamylation of proteins in cyanate solutions (entire document).

Claim 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Crompton et al. (Exp. Eye Res. Vol. 40 (1985), pgs. 297-311).

Crompton et al. teach the use of aspirin to inhibit or delay carbamylation of proteins in cyanate solutions (entire document).

Claim 1 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Barri et al. (US 2003/0045004 A1).

Barri et al. teach the use of monomeric amino acids (e.g. lysine, glycine, arginine) and other enzymatic or non-enzymatic inhibitors of carbamylation, to inhibit or delay carbamylation of proteins in a urea or cyanate containing solution (abstract, para's 12, 28, 39-40, and claims 7-9, 18-19).

[As to rejections of claim 12 above, it is noted that the compounds used in therein inherently possess a buffering capacity of about neutral, absent evidence to the contrary].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-9, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Roberts et al. (Exp. Eye Res. Vol. 50 (1990), pgs. 157-164), Lewis et al. (Exp. Eye Res. Vol. 43 (1986) , pgs. 973-979), Crompton et al. (Exp. Eye Res. Vol. 40 (1985), pgs. 297-311), or Barri et al. (US 2003/0045004 A1).

The four (4) references are all discussed above. The references teach inhibiting and/or delaying carbamylation of peptides using compounds other than ethylene diamine like compound. However, the references do not expressly teach a process using the term "solubilizing" or "purifying" said peptide (claims 4-5). The references do not expressly teach the protein to be ribonuclease or RNase A (claims 6-7). The references do not expressly teach carbamylation percent protection of about 100% after three weeks, a compound concentration within the broad range of 1-150mM, or cyanate in the solution at a concentration of about 5mM (claims 8-9, and 11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to "solubilize" or "purify" the peptides being inhibited or delayed from carbamylation in any of the references above, because these "terms of art" are merely known objectives (solubilizing/purifying) to one of skill in the art in general peptide preparation, and more

specifically are the desired end result beneficially taught by references, by using the underlying intermediate step of inhibiting or delaying carbamylation of peptides.

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply inhibiting or delaying carbamylation to the specific peptide/protein of ribonuclease/RNase A in any of the references above, because these are merely well known peptides in the art which the references' teachings were expected to be applied, like the peptides of example the references beneficially taught the inhibition or delaying of carbamylation therein.

If not inherently in the references, it would have been obvious to one of ordinary skill in the art at the time of the invention to arrive at a carbamylation percent protection of about 100% after three weeks, a compound concentration within the broad range of 1-150mM, and cyanate in the solution at a concentration of about 5mM, in the references above, because the references all advantageously teach the use of like compounds to carry out the decarbamylation of peptides (the underlying process), and arriving at the above ranges to carry out the same process is merely a matter of routine optimization by one of ordinary skill in the art, depending on the desired effect.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Objection and Indication of Allowable Subject Matter

Claims 2-3 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 2-3, and 10, as drawn to a method for inhibiting and/or delaying carbamylation of a peptide using the three (3) specifically claimed monomeric amino acids or two (2) dipeptides of claims 2 and 10, or dipeptides generally (claim 3); are not reasonably taught or suggested by the prior art of record.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA
09/30/05

CHRISTOPHER R. TATE
PRIMARY EXAMINER